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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/063,477	04/20/1998	ROBERT A. HOLTON	FSU-10302	4505
321	7590	03/06/2006	EXAMINER	
SENNIGER POWERS ONE METROPOLITAN SQUARE 16TH FLOOR ST LOUIS, MO 63102			DESAI, RITA J	
		ART UNIT	PAPER NUMBER	
		1625		

DATE MAILED: 03/06/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/063,477	HOLTON ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Rita J. Desai	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 16 December 2005.
- 2a) This action is FINAL.                            2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1 and 3-19 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) \_\_\_\_\_ is/are allowed.
- 6) Claim(s) 1 and 3-19 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
  1. Certified copies of the priority documents have been received.
  2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- 1) Notice of References Cited (PTO-892)
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date 10/11/2005.
- 4) Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- 5) Notice of Informal Patent Application (PTO-152)
- 6) Other: \_\_\_\_\_.

## **DETAILED ACTION**

Claims 1-19 are pending.

The rejection of claims 1,3-5 under 35 USC 102 over Kant et al has been withdrawn , since applicant's have amended the claims to clearly specify that the starting taxane has C(7) and C(10) hydroxyl groups and only the (C10 ) is selectively acylated..

The rejection of the claims 1-19 under 35 USC 103 over F. Gueritte-Voegelein et al and Kant et al is also withdrawn now since applicants have amended the claims the prior art does not teach a selective acylation in 1M or less of base. The starting taxol is also not a 7 and 10 hydroxy form.

### **New grounds of Rejection**

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-19 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

To satisfy the Written description requirement, applicant must convey with reasonable clarity to one skilled in the art, as of the filing date that applicant were in possession of the claimed invention. Applicant's claims are drawn to a process of making taxane derivatives

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wherein the X<sub>2</sub>, X<sub>3</sub>, X<sub>4-X14</sub> and Z<sub>9</sub> have hydrocarbyl substituted hydrocarbyl, hetero aryl groups as substitutions. The specification on pages 6 and 7 have the recitation of the hydrocarbyl and heteroaryl. There is no definition given to these groups. **The specification gives no guidance to one of ordinary skill in the art which groups are encompassed by this definition.** The next one is protective group. The specification again does not define the groups in this category. The generic groups includes plethora of compounds, which has this functional moieties.

The expression “hydrocarbyl, hetero aromatic , protective group” without i.e. partial or complete definition does not convey to one of ordinary skill in the art that applicants were in possession of the claimed subject matter. The functional language recited without any correlation does not meet the written description requirement for the expression “hydrocarbyl, hetero aromatic , protective group “ as one of ordinary skill in the art could not recognize or understand the structure from the mere recitation of the function. Claims employing functional language at the point of novelty, such as applicants’, neither provide those elements required to practice the inventions, nor “inform the public” during the life of the patent of the limits of the monopoly asserted. The expression could encompass a myriad of compounds and applicants claimed expression represents only an *invitation to experiment regarding possible compounds.*

#### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

- (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sisti US 5750736.

Applicants claim is drawn to a process of selective acylation of the C(10) hydroxyl group in less than 1 equivalent of a base.

Determination of the scope and content of the prior art (MPEP §2141.01)

The Sisti reference uses the C(7) and C(10) hydroxyl taxol and selectively acylates the C(10) group.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The reference uses n-butyl lithium in atleast 1 equivalent amount for the process.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The reference proceeds with the same reaction and uses the same reagents , starting material solvent. Modifying the conditions by decreasing the base is not patentably distinct in the absence of a showing of unexpected results. The specification do not have any showing that by using less base the reaction/process has any unexpected results.

### ***Conclusion***

Claims 1-19 are not found to be allowable.

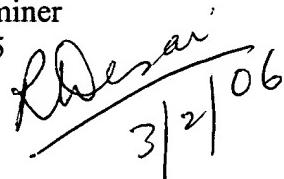
Jean-Noel Denis also uses a base more than 1 equivalent..

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rita J. Desai whose telephone number is 571-272-0684. The examiner can normally be reached on Monday - Friday, 9:30 am to 6:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Rita J. Desai  
Primary Examiner  
Art Unit 1625



3/2/06

R.D.  
March 2nd, 2006.